Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Species/Strain: MICE/B6C3F1 Pathologist: RYAN, M. - Blackshear, P.

F1_M3

C Number: C88123B

Lock Date: 05/24/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Date Report Reqsted: 05/04/2006

Time Report Reqsted: 11:47:08
First Dose M/F: 10/04/01 / 10/03/01

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths	30	00	00	00
Moribund Sacrifice	4	8	6	14
Natural Death	7		8	3
Survivors				
Terminal Sacrifice	39	42	36	33
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	(50)	(30)	1 [2.0]	(50)
Muscularis, Inflammation, Chronic	1 [2.0]		1 [2.0]	
Gallbladder	(45)	(48)	(45)	(46)
Cyst	(10)	1 [1.0]	(10)	(10)
Inflammation, Chronic		1 [1.0]	1 [1.0]	3 [2.0]
Ulcer		. []	. []	1 [2.0]
Epithelium, Cytoplasmic Alteration		1 [3.0]		2 [3.5]
Epithelium, Hyperplasia		1 [2.0]	2 [2.0]	1
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Edema	, ,	1 [3.0]	` '	. ,
Hemorrhage			1 [3.0]	
Artery, Inflammation, Chronic			1 [2.0]	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Hemorrhage			1 [3.0]	
Artery, Inflammation, Chronic	1 [2.0]			
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	(=0)	1 [2.0]	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	1 [1.0]			4 [0.0]
Epithelium, Hyperplasia, Focal	(50)	(50)	(50)	1 [2.0]
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum Inflammation, Granulomatous	(50)	(50)	(50)	(50)
Inflammation, Grandomatous		1 [2.0]		1 [1.0]

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Liver	(50)	(50)	(50)	(50)	
Angiectasis	(00)	()	1 [2.0]	()	
Basophilic Focus	2	4	3	4	
Clear Cell Focus	29	27	21	8	
Eosinophilic Focus	16	21	14	9	
Fatty Change	31 [1.6]	25 [1.4]	15 [1.3]	1 [1.0]	
Fibrosis		- 1		1 [2.0]	
Hematopoietic Cell Proliferation	1 [1.0]			. [=.•]	
Hepatodiaphragmatic Nodule	. []			1	
Inflammation, Acute	1 [1.0]			1 [1.0]	
Inflammation, Chronic	16 [1.2]	16 [1.3]	11 [1.3]	15 [1.3]	
Mineralization	1 [1.0]	1 [2.0]	[0]		
Mixed Cell Focus	10	12	13	11	
Necrosis	5 [1.8]	9 [1.8]	7 [1.9]	11 [2.0]	
Tension Lipidosis	4 [1.0]	5 [1.0]	1 [1.0]	6 [1.0]	
Bile Duct, Dilatation	. [0]	1 [1.0]	. [0]	0 [0]	
Bile Duct, Hyperplasia		1 [2.0]			
Centrilobular, Degeneration	1 [3.0]	. [=]			
Centrilobular, Necrosis	1 [2.0]			1 [2.0]	
Serosa, Hyperplasia	. [=.0]	1 [4.0]		. [=.•]	
Vein, Thrombosis		. [•]		1 [3.0]	
Mesentery	(3)	(1)	(1)	(1)	
Inflammation, Chronic	1 [3.0]	()	(.)	(.)	
Artery, Inflammation, Chronic	1 [2.0]		1 [2.0]		
Fat, Necrosis	1 [2.0]	1 [2.0]	. [=.0]		
Oral Mucosa	(7)	(5)	(5)	(7)	
Inflammation, Chronic	()	(0)	(5)	1 [2.0]	
Gingival, Inflammation, Chronic	7 [1.6]	5 [1.6]	5 [1.6]	6 [1.8]	
Pancreas	(50)	(50)	(50)	(50)	
Acinus, Atrophy	1 [1.0]	3 [1.3]	()	2 [1.5]	
Acinus, Cytoplasmic Alteration	. []	1 [1.0]	1 [2.0]	1 [1.0]	
Duct, Cyst		,	1 [3.0]	1 [1.0]	
Duct, Inflammation, Chronic		1 [1.0]	1	,	
Salivary Glands	(50)	(50)	(50)	(50)	
Inflammation, Granulomatous	1 [1.0]	(/	()	()	
Artery, Parotid Gland, Inflammation,	. []		1 [1.0]		
Chronic			. []		
Artery, Parotid Gland, Mineralization			1 [2.0]	1 [2.0]	
Parotid Gland, Atrophy			. [=,0]	1 [2.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)	

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Hemorrhage			1 [2.0]		
Inflammation, Chronic	1 [2.0]				
Ulcer	1 [2.0]		1 [1.0]	1 [2.0]	
Artery, Inflammation, Chronic	1 [2.0]		4 [4 0]		
Epithelium, Hyperplasia, Focal Epithelium, Vacuolization Cytoplasmic	1 [2.0]	1 [2.0]	1 [1.0]		
Stomach, Glandular	(50)	(50)	(50)	(50)	
Hemorrhage, Acute	(00)	1 [2.0]	(00)	(88)	
Inflammation, Chronic		,	4 [1.0]	1 [1.0]	
Mineralization			1 [1.0]		
Ulcer			1 [2.0]	3 [1.7]	
Epithelium, Glands, Ectasia		1 [1.0]	4 [0.0]		
Epithelium, Glands, Hyperplasia, Focal Epithelium, Hyperplasia, Focal		1 [0 0]	1 [2.0]		
Glands, Ectasia		1 [2.0] 1 [1.0]	2 [1.5]	2 [1.0]	
Tooth	(15)	(14)	(9)	(2)	
Dysplasia	2 [3.0]	1 [2.0]	2 [2.0]	(=)	
Malformation	14 [1.9]	13 [2.1]	7 [1.4]	2 [1.5]	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Aorta, Inflammation, Chronic	1 [3.0]				
Heart	(50)	(50)	(50)	(50)	
Thrombosis	4 [4 0]	4 [4 0]	0.10.01	1 [4.0]	
Artery, Inflammation, Chronic Atrium, Thrombosis	1 [1.0] 1 [3.0]	1 [1.0] 1 [4.0]	2 [3.0]	3 [3.7]	
Epicardium, Hyperplasia	1 [3.0] 1 [1.0]	1 [4.0]		3 [3.7]	
Epicardium, Infiltration Cellular,	1 [1.0]				
Mononuclear Cell	. []				
Myocardium, Infiltration Cellular,	9 [1.0]	10 [1.0]	2 [1.5]	12 [1.1]	
Mononuclear Cell					
Myocardium, Mineralization	0.14.01	4 [4 0]	2 [1.5]	2 [1.5]	
Myocardium, Necrosis	3 [1.0]	1 [1.0]	1 [2.0]	4 [1.5]	
Myocardium, Necrosis, Focal Nerve, Inflammation, Chronic		1 [1.0]		1 [1.0]	
Ventricle, Atrophy			1 [4.0]	1 [1.0]	
ventuole, Auopity			י ניטן		

ENDOCRINE SYSTEM

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Adrenal Cortex	(50)	(50)	(49)	(50)	
Angiectasis	(00)	1 [1.0]	1 [1.0]	1 [1.0]	
Hyperplasia	2 [1.5]	1 [1.0]	1 [1.0]	2 [1.0]	
Hypertrophy	15 [1.3]	17 [1.1]	17 [1.2]	13 [1.2]	
Pigmentation	1 [1.0]	17 [1.1]	17 [1.2]	2 [1.0]	
Vacuolization Cytoplasmic	1 [1.0]			1 [1.0]	
Vacuolization Cytoplasmic, Focal	17 [1.3]	14 [1.1]	11 [1.2]	16 [1.2]	
Subcapsular, Hyperplasia	50 [1.5]	49 [1.2]	42 [1.2]	45 [1.2]	
Subcapsular, Hypertrophy, Focal	1 [1.0]	49 [1.2]	72 [1.2]	43 [1.2]	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia, Focal	2 [1.0]	1 [1.0]	1 [2.0]	3 [1.3]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	35 [1.4]	24 [1.3]	24 [1.3]	9 [1.3]	
Parathyroid Gland	(43)	(39)	(46)	(47)	
Right, Atrophy	(43)	(39)	(40)	1 [2.0]	
Pituitary Gland	(50)	(50)	(50)	(49)	
Angiectasis	1 [2.0]	(50)	(30)	(49)	
Cyst	5 [1.0]	2 [1.0]	2 [1.0]	2 [1.0]	
Pars Distalis, Hyperplasia, Focal	3 [1.3]	4 [1.5]	2 [1.0] 1 [1.0]	2 [1.0]	
Thyroid Gland	(50)	4 [1.5] (50)	(50)	(50)	
Cyst	2 [1.0]		2 [1.0]	5 [1.2]	
Inflammation, Granulomatous		3 [1.0]	2 [1.0]	5 [1.2]	
Inflammation, Chronic	1 [1.0]	1 [1 0]		1 [2 0]	
C-cell, Hyperplasia		1 [1.0]		1 [2.0]	
	1 [2 0]			1 [1.0]	
Follicle, Hyperplasia	1 [3.0]	45 [4 5]	0 [4 4]	0.[4.5]	
Follicle, Hyperplasia, Focal	12 [1.3]	15 [1.5]	8 [1.4]	8 [1.5]	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Enididumia	(50)	/FO\	(50)	(50)	
Epididymis	(50)	(50)	(50)	(50)	
Granuloma Sperm	1 [3.0]	1 [2.0]		3 [2.0]	
Inflammation, Chronic	1 [1.0]	4 [0 0]		1 [3.0]	
Artery, Inflammation, Chronic	(50)	1 [2.0]	(50)	(50)	
Preputial Gland	(50)	(50)	(50)	(50)	
Cyst	19 [2.0]	11 [2.0]	11 [2.3]	10 [2.1]	

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Infiltration Cellular, Lymphoid			1 [3.0]		
Infiltration Cellular, Chronic				1 [3.0]	
Inflammation, Suppurative				1 [2.0]	
Inflammation, Granulomatous	1 [2.0]	1 [2.0]			
Inflammation, Chronic	1 [2.0]	4 [2.3]		1 [2.0]	
Duct, Cyst		1 [2.0]			
Prostate	(50)	(50)	(50)	(50)	
Infiltration Cellular, Lymphoid	4 50 01	4 [0.0]	1 [2.0]	4.54.03	
Inflammation, Suppurative	1 [2.0]	1 [2.0]	4 [0 0]	1 [1.0]	
Inflammation, Chronic Seminal Vesicle	(50)	1 [2.0]	1 [2.0]	(50)	
Atrophy	(50)	(50)	(50)	(50)	
Fibrosis	1 [2.0]		1 [2.0]	2 [2.5]	
Inflammation, Suppurative	1 [4.0]		1 [2.0]		
Inflammation, Chronic	1 [4.0]	1 [2.0]			
Testes	(50)	(50)	(50)	(50)	
Granuloma Sperm	(66)	(00)	(66)	1	
Artery, Inflammation, Chronic	1 [2.0]		1 [1.0]		
Artery, Mineralization		2 [1.0]	5 [1.4]	35 [1.6]	
Artery, Thrombosis			1 [4.0]		
Germinal Epithelium, Degeneration	1 [3.0]	4 [1.5]	1 [2.0]	4 [1.8]	
Germinal Epithelium, Inflammation,				1 [2.0]	
Chronic					
Germinal Epithelium, Mineralization		1 [2.0]	1 [2.0]		
Tunic, Inflammation, Chronic	1 [1.0]		= t4 o3	1 [1.0]	
Tunic, Mineralization	1 [1.0]		5 [1.0]	27 [1.8]	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hyperplasia	34 [1.0]	39 [1.0]	35 [1.0]	34 [1.1]	
Lymph Node	(4)	(2)	(1)	(1)	
Bronchial, Hyperplasia, Lymphoid	1 [3.0]				
Lumbar, Hyperplasia, Lymphoid	1 [3.0]				
Mediastinal, Hyperplasia, Lymphoid	2 [3.0]	4 [4 0]			
Pancreatic, Hyperplasia	2 [2 5]	1 [4.0]			
Renal, Hyperplasia, Lymphoid Lymph Node, Mandibular	2 [3.5] (49)	(48)	(49)	(48)	
Atrophy	(4 9) 11 [2.0]	(48) 5 [2.4]	6 [2.5]	(48) 13 [2.3]	
Allophy	11[2.0]	ა [Հ. 4]	ช [८.၁]	ای [۲.۵]	

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Hematopoietic Cell Proliferation	1 [1.0]				
Hyperplasia, Lymphoid	2 [2.0]	5 [2.2]	5 [2.0]	2 [2.0]	
Necrosis, Lymphoid	2 [2.0]			1 [1.0]	
Lymph Node, Mesenteric	(50)	(47)	(50)	(49)	
Atrophy	10 [1.9]	3 [2.7]	6 [2.3]	14 [1.9]	
Hyperplasia, Lymphoid	4 [2.3]	1 [3.0]	4 [2.3]	1	
Necrosis, Lymphoid	1 [2.0]	[]	1 [1.0]	1 [1.0]	
Spleen	(50)	(50)	(50)	(50)	
Atrophy	2 [4.0]	6 [2.5]	3 [3.0]	7 [1.6]	
Hematopoietic Cell Proliferation	14 [2.1]	14 [2.2]	20 [1.9]	28 [2.0]	
Hyperplasia, Plasma Cell	1 [2.0]	[=.=]	[]	[]	
Lymphoid Follicle, Hyperplasia	4 [1.5]	1 [2.0]	4 [2.5]		
Lymphoid Follicle, Necrosis	1 [2.0]	. []	. [=]		
Thymus	(47)	(46)	(50)	(46)	
Atrophy	41 [2.2]	39 [2.5]	37 [2.7]	44 [3.2]	
Cyst	19 [1.2]	9 [1.0]	15 [1.2]	9 [1.0]	
Ectopic Parathyroid Gland	[]	5 [5]	1 [1.0]	2 []	
Hyperplasia, Lymphoid	1 [2.0]		2 [2.0]		
Necrosis	1 [1.0]		_ []		
Epithelial Cell, Hyperplasia	. []		1 [2.0]		
INTEGUMENTARY SYSTEM					
Skin	(50)	(50)	(50)	(50)	
Ulcer	(50)	(30)	(30)	3 [3.0]	
Subcutaneous Tissue, Edema				1 [3.0]	
Subcutaneous Tissue, Edema Subcutaneous Tissue, Inflammation,	1 [1.0]			1 [3.0]	
Chronic	1 [1.0]				
Subcutaneous Tissue, Necrosis			1 [3.0]		
Subcutaneous Tissue, Necrosis			1 [3.0]		
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Hyperostosis	1 [2.0]	2 [2.0]	2 [2.0]	3 [2.0]	
Cranium, Hyperplasia	ا رح.ن	1 [2.0]	ک زک.ن	J [2.0]	
Skeletal Muscle	(1)	(1)	(0)	(2)	
Inflammation, Granulomatous	1 [2.0]	(1)	(0)	(-)	
	. [0]				

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Compression	1 [3.0]				
Cyst Epithelial Inclusion	1	4 [0 0]			
Hemorrhage, Acute	4 [0 0]	1 [3.0]			
Hydrocephalus Necrosis	1 [2.0]	4 [0 0]			
Artery, Inflammation, Chronic		1 [2.0] 1 [2.0]	1 [2.0]		
Meninges, Ventricle, Inflammation,	1 [2.0]	1 [2.0]	1 [2.0]		
Granulomatous	1 [2.0]				
Meninges, Infiltration Cellular,		1 [2.0]			
Lymphocyte		. [=.0]			
Vein, Infiltration Cellular, Mononuclear		1 [2.0]			
Cell					
Peripheral Nerve	(0)	(0)	(1)	(0)	
Axon, Degeneration			1 [3.0]		
Spinal Cord	(0)	(0)	(1)	(0)	
Hemorrhage			1 [2.0]		
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Fibrosis	1 [1.0]				
Inflammation, Chronic			3 [1.3]	1 [2.0]	
Metaplasia, Osseous			2 [1.0]		
Alveolar Epithelium, Hyperplasia	2 [1.0]	1 [1.0]	4 [3.3]	2 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]		1 [2.0]	8 [1.5]	
Arteriole, Thrombosis	1 [2.0]				
Artery, Mineralization	1 [1.0]				
Bronchus, Hypertrophy Serosa, Inflammation, Chronic	1 [2.0]			1 [2.0]	
Nose	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	4 [2.3]	4 [1.0]	1 [2.0]	1 [1.0]	
Inflammation, Chronic	∓ [∠.∪]	2 [1.0]	1 [1.0]	1 [1.0]	
Polyp, Inflammatory	1 [2.0]	1 [2.0]	1 [2.0]	. []	
Glands, Hyperplasia	. []	. [=.0]	. []	1 [2.0]	
/ / /				· r=1	
Glands, Hyperplasia, Focal	1 [2.0]				

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Nasolacrimal Duct, Infiltration Cellular,	2 [1.0]	5 [1.4]	2 [2.0]	2 [1.0]	
Polymorphonuclear Nasopharyngeal Duct, Inflammation, Chronic				1 [1.0]	
Olfactory Epithelium, Amyloid Deposition Olfactory Epithelium, Atrophy, Focal Olfactory Epithelium, Metaplasia	1 [2.0] 8 [1.6] 1 [3.0]	5 [1.6]	1 [3.0]	2 [2.0]	
Olfactory Epithelium, Metaplasia, Focal Respiratory Epithelium, Atrophy, Focal		1 [1.0] 2 [1.0]			
Respiratory Epithelium, Hyperplasia, Focal	1 [1.0]	1 [1.0]	1 [1.0]		
Respiratory Epithelium, Metaplasia, Squamous Vomeronasal Organ, Infiltration Cellular,	2 [1.0]	1 [1.0] 10 [1.0]	3 [1.0]	4 [1.0]	
Polymorphonuclear Pleura	(1)	(0)	(0)	(0)	
Hyperplasia	1 [2.0]				
SPECIAL SENSES SYSTEM					
Eye Degeneration Anterior Chamber, Inflammation, Suppurative	(50)	(50)	(50)	(50) 1 [3.0] 1 [3.0]	
Cornea, Inflammation, Chronic Harderian Gland Hyperplasia, Focal	3 [1.7] (50) 4 [1.8]	(50) 8 [1.8]	2 [1.0] (50) 5 [2.0]	1 [1.0] (50) 10 [1.8]	
RINARY SYSTEM					
Kidney Casts Protein	(50) 1 [3.0]	(50)	(50)	(50)	
Fibrosis, Focal Infarct Inflammation, Suppurative	1 [1.0]	1 [1.0]	1 [1.0] 3 [1.3]	1 [1.0]	
Inflammation, Chronic Metaplasia, Osseous	1 [1.0]	2 [3.0] 1 [1.0]	3 [1.3]	1 [1.0] 4 [1.0]	
Mineralization Necrosis	16 [1.0]	15 [1.0]	2 [1.0]	5 [1.0] 1 [3.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Regsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Nephropathy	43 [1.3]	46 [1.2]	41 [1.3]	45 [1.4]	
Artery, Inflammation, Chronic	2 [2.5]	1 [3.0]	1 [3.0]		
Glomerulus, Inflammation, Chronic	1 [3.0]				
Glomerulus, Necrosis, Fibrinoid	1 [4.0]				
Papilla, Necrosis	1 [2.0]				
Pelvis, Inflammation, Suppurative	1 [3.0]			2 [2.0]	
Renal Tubule, Accumulation, Hyaline Droplet	1 [2.0]				
Renal Tubule, Cyst	8 [1.0]	5 [1.2]	4 [1.3]	5 [1.0]	
Renal Tubule, Hyperplasia	1 [1.0]	2 [1.5]	5 [1.0]	1 [1.0]	
Renal Tubule, Mineralization			1 [1.0]		
Vein, Infiltration Cellular, Lymphocyte		1 [4.0]			
Urinary Bladder	(50)	(50)	(50)	(50)	
Infiltration Cellular, Lymphoid	1 [3.0]	` ,	1 [2.0]	,	
Inflammation, Suppurative	1 [2.0]				
Inflammation, Chronic		2 [2.5]		1 [1.0]	
Artery, Inflammation, Chronic	1 [2.0]		1 [3.0]	• •	
Artery, Mineralization	1 [2.0]				
Transitional Epithelium, Hyperplasia	1 [3.0]				

^{***} END OF MALE ***

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

	0.110///-	00 877 777	40.000	00.000
B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			1	
Moribund Sacrifice	7	8	8	8
Natural Death	5	3	10	3
Survivors		4		
Natural Death Terminal Sacrifice	38	1 38	31	39
Animals Examined Microscopically	50	50	50	50
Animais Examined inicroscopically	30	30	30	30
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Inflammation, Suppurative	(00)	(00)	1 [3.0]	(00)
Perforation			1	
Gallbladder	(47)	(45)	(46)	(49)
Cyst	1 [1.0]	. ,	, ,	` ,
Inflammation, Chronic	1 [1.0]			
Epithelium, Cytoplasmic Alteration				1 [2.0]
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Edema	1 [3.0]		4 50 01	
Lymphoid Tissue, Hyperplasia, Lymphoid	(50)	(EQ)	1 [2.0]	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum Serosa, Inflammation, Chronic	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	1 [2.0] (50)	(50)
Inflammation, Chronic	1 [1.0]	(30)	(30)	(30)
Epithelium, Hyperplasia, Focal	1 [2.0]			
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Epithelium, Cyst	1	(/	(/	ζ /
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Artery, Peyer's Patch, Mineralization		• •	1 [2.0]	
Epithelium, Hyperplasia, Focal				1 [2.0]
Liver	(50)	(50)	(50)	(50)
Angiectasis			2 [2.5]	0
Basophilic Focus			1	2

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Regsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Clear Cell Focus	3	2	2	2	
Eosinophilic Focus	12	15	8	7	
Fatty Change	6 [1.5]	7 [1.3]	4 [1.0]	2 [1.5]	
Hematopoietic Cell Proliferation	3 [1.7]	4 [2.3]	1 [1.0]	1 [1.0]	
Infarct	- []	. []	1 [3.0]	. []	
Inflammation, Chronic	29 [1.0]	27 [1.0]	21 [1.0]	21 [1.0]	
Mineralization	_0[0]	[]	=:[::0]	1 [2.0]	
Mixed Cell Focus	4	5	4	6	
Necrosis	1 [2.0]	9	•	2 [2.0]	
Tension Lipidosis	3 [1.0]	9 [1.0]	5 [1.0]	6 [1.0]	
Centrilobular, Necrosis	0 [1.0]	3 [1.0]	1 [2.0]	0 [1.0]	
Centrilobular, Vacuolization Cytoplasmic	1 [2.0]		1 [2.0]		
Mesentery	(8)	(3)	(8)	(2)	
Fat, Necrosis	5 [2.2]	3 [2.3]	8 [2.4]	2 [2.0]	
Oral Mucosa	(1)	(0)	(0)	(0)	
Gingival, Inflammation, Chronic	1 [1.0]	(0)	(0)	(0)	
Pancreas	(49)	(49)	(50)	(50)	
Hyperplasia, Lymphoid	(49)	(49)	1 [2.0]	(50)	
Inflammation, Chronic			2 [1.0]		
Acinus, Atrophy		4 [4 0]		2 [4 0]	
	4 [4 0]	1 [1.0]	3 [1.3]	2 [1.0]	
Acinus, Cytoplasmic Alteration	1 [1.0]		4 [2 0]	1 [2.0]	
Artery, Thrombosis			1 [3.0]	2 [4 7]	
Duct, Cyst			1 [3.0]	3 [1.7]	
Duct, Cytoplasmic Alteration	4.54.03		4 [4 0]	1 [2.0]	
Duct, Inflammation, Chronic	1 [1.0]	(50)	1 [1.0]	(50)	
Salivary Glands	(49)	(50)	(50)	(50)	
Atrophy, Diffuse				1 [2.0]	
Parotid Gland, Atrophy	(==)	1 [2.0]	1 [3.0]	(==)	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Inflammation, Chronic	1 [2.0]			4.54.01	
Epithelium, Hyperplasia	1 [2.0]	(==)	(==)	1 [1.0]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Inflammation, Chronic	1 [1.0]	1 [1.0]		1 [1.0]	
Ulcer		1 [2.0]			
Epithelium, Glands, Cytoplasmic	1 [1.0]			1 [2.0]	
Alteration					
Epithelium, Glands, Hyperplasia				1 [2.0]	
Glands, Ectasia	1 [2.0]				
Glands, Hyperplasia	1 [1.0]				
Tooth	(0)	(0)	(0)	(1)	

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Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Regsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Malformation				1 [2.0]	
CARDIOVASCULAR SYSTEM					
Heart	(50)	(50)	(50)	(50)	
Artery, Inflammation, Chronic Atrium, Thrombosis	2 [1.5]		1 [2.0]	1 [4.0]	
Coronary Artery, Inflammation, Chronic	1 [4.0]		1 [2.0]	1 [4.0]	
Myocardium, Infiltration Cellular, Mononuclear Cell	2 [1.0]	7 [1.3]	4 [1.0]	3 [1.0]	
Myocardium, Mineralization		3 [1.7]	1 [2.0]		
Myocardium, Necrosis			1 [1.0]		
Ventricle, Thrombosis				1 [2.0]	
ENDOCRINE SYSTEM					
Adrenal Cortex	(49)	(50)	(49)	(50)	
Angiectasis		1 [2.0]		4 [0 0]	
Atrophy Hematopoietic Cell Proliferation	1 [2.0]	1 [1.0]		1 [2.0]	
Hyperplasia	1 [2.0]	2 [2.0]		1 [1.0]	
Hypertrophy	1 [1.0]	1 [2.0]	4 [1.0]		
Pigmentation		3 [1.0]			
Vacuolization Cytoplasmic, Focal	3 [1.0]	40 [4 0]	2 [1.0]	40 [4 0]	
Subcapsular, Hyperplasia Adrenal Medulla	49 [1.8] (50)	49 [1.9] (50)	48 [1.8] (50)	49 [1.8] (50)	
Angiectasis	(30)	1 [1.0]	(30)	(30)	
Hyperplasia, Focal	1 [3.0]	4 [1.5]	1 [2.0]	2 [1.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	1 [1.0]	1 [1.0]	4 [1.0]	()	
Parathyroid Gland	(42)	(32)	(35)	(42)	
Cyst	1 [1.0]	, ,		2 [1.0]	
Pituitary Gland	(50)	(50)	(49)	(50)	
Angiectasis	2 [1.5]	1 [1.0]			
Cyst	3 [1.3]	4 [1.3]		1 [1.0]	
Fibrosis		1 [2.0]			
Hemorrhage, Chronic		1 [2.0]			
Pars Distalis, Hyperplasia, Focal	11 [1.5]	11 [1.5]	10 [1.6]	10 [1.6]	
Pars Intermedia, Hyperplasia, Focal	1 [1.0]		1 [2.0]	1 [1.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Reqsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Thyroid Gland	(49)	(50)	(50)	(50)	
Cyst Infiltration Cellular, Lymphoid Inflammation, Suppurative	1 [1.0]	1 [1.0] 1 [3.0] 2 [1.0]	2 [1.0]		
Inflammation, Granulomatous	4.54.03		4.54.03	1 [1.0]	
Inflammation, Chronic Follicle, Hyperplasia, Focal	1 [1.0] 14 [1.4]	1 [1.0] 6 [1.5]	1 [1.0] 10 [1.3]	5 [1.4]	
SENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland Duct, Cyst	(50)	(50)	(49)	(50) 1 [2.0]	
Ovary	(50)	(50)	(50)	(49)	
Angiectasis	2 [2.0]	2 [2.5]	1 [2.0]	2 [2.0]	
Cyst	24 [1.4]	19 [1.5]	11 [1.6]	23 [1.2]	
Mineralization		1 [2.0]			
Thrombosis	1 [3.0]	1 [3.0]	2 [4.0]	2 [1.5]	
Bilateral, Thrombosis	1 [4.0]				
Follicle, Atrophy	33 [2.5]	29 [2.3]	35 [2.2]	37 [2.5]	
Uterus	(50)	(50)	(50)	(50)	
Angiectasis Dilatation		2 [1.5]	2 [2.5]	1 [3.0]	
Inflammation, Suppurative	1 [4.0]	1 [1.0]		2 [3.0]	
Inflammation, Chronic Active	1 [4.0]	1 [1.0]		1 [2.0]	
Thrombosis			1 [4.0]	. [2.0]	
Endometrium, Hyperplasia, Cystic	45 [1.7]	48 [1.5]	45 [1.6]	42 [1.5]	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Atrophy Hyperplasia	8 [1.1]	10 [1.1]	13 [1.1]	1 [3.0] 5 [1.2]	
Infiltration Cellular, Histiocyte Lymph Node	1 [2.0]	(4)	(6)	<i>(</i> 5)	
Lymph Node	(8)	(4)	(6)	(5)	

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Regsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Bronchial, Hyperplasia, Lymphoid		1 [3.0]			
Iliac, Necrosis		1 [3.0]			
Lumbar, Hematopoietic Cell Proliferation	1 [2.0]	. []			
Lumbar, Hyperplasia, Lymphoid	1 [2.0]				
Mediastinal, Hematopoietic Cell	1 [2.0]				
Proliferation	1				
Mediastinal, Hyperplasia, Lymphoid	2 [3.0]				
Mediastinal, Inflammation, Chronic			1 [3.0]		
Renal, Hyperplasia, Lymphoid	1 [3.0]				
Lymph Node, Mandibular	(49)	(50)	(50)	(50)	
Atrophy	3 [1.3]	2 [1.5]	6 [1.7]	4 [2.0]	
Hematopoietic Cell Proliferation	1 [1.0]	1 [1.0]			
Hyperplasia, Lymphoid	8 [2.1]		5 [2.6]	6 [2.3]	
Necrosis, Lymphoid	1 [1.0]		1 [3.0]		
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)	
Atrophy	7 [1.3]	9 [1.2]	8 [1.5]	7 [1.9]	
Hematopoietic Cell Proliferation	1 [2.0]				
Hyperplasia, Lymphoid	4 [2.0]	1 [2.0]	4 [2.3]	3 [2.0]	
Infiltration Cellular, Polymorphonuclear			1 [2.0]		
Inflammation, Suppurative				1 [2.0]	
Necrosis, Lymphoid	2 [1.5]	1 [2.0]	1 [2.0]		
Spleen	(50)	(49)	(49)	(50)	
Atrophy	1 [2.0]	2 [1.5]	1 [2.0]	2 [2.5]	
Hematopoietic Cell Proliferation	17 [2.6]	17 [2.2]	15 [2.7]	8 [2.8]	
Hyperplasia, Lymphoid				3 [2.7]	
Hyperplasia, Plasma Cell	1 [2.0]		1 [2.0]		
Lymphoid Follicle, Hyperplasia	3 [3.0]	4 [2.0]		2 [2.0]	
Lymphoid Follicle, Necrosis	3 [2.0]			1 [1.0]	
Thymus	(49)	(50)	(49)	(50)	
Angiectasis				1 [2.0]	
Atrophy	16 [2.4]	19 [2.3]	12 [2.5]	17 [2.4]	
Cyst	7 [1.1]	9 [1.1]	7 [1.0]		
Hyperplasia, Lymphoid	9 [1.6]	11 [1.8]	7 [2.0]	8 [1.6]	
Necrosis, Lymphoid	1 [2.0]	1 [2.0]	1 [2.0]		
ITEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Hyperplasia, Cystic	1 [1.0]	1 [1.0]	,	,	

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Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Skin Cyst Epithelial Inclusion Inflammation, Granulomatous Ulcer	(50)	(50)	(50) 1 [1.0] 1 [3.0] 2 [3.0]	(50)	
MUSCULOSKELETAL SYSTEM					
Bone Atrophy Hyperostosis Skeletal Muscle Fibrosis Inflammation, Chronic	(50) 3 [1.7] (2)	(50) 6 [1.7] (5) 3 [2.0]	(50) 3 [1.3] (5) 1 [1.0]	(50) 1 [3.0] 2 [2.0] (0)	
NERVOUS SYSTEM					
Brain Arteriole, Inflammation, Chronic Artery, Meninges, Inflammation, Chronic	(50) 1 [2.0]	(50)	(50)	(50) 1 [1.0]	
Hypothalamus, Compression Meninges, Infiltration Cellular, Lymphocyte	1 [3.0] 2 [1.5]	2 [3.5]	1 [3.0] 1 [2.0]	. [•]	
Vein, Infiltration Cellular, Lymphocyte Spinal Cord Hemorrhage	1 [1.0] (1) 1 [1.0]	(0)	(0)	(0)	
RESPIRATORY SYSTEM					
Lung Hematopoietic Cell Proliferation Inflammation, Granulomatous Inflammation, Focal, Chronic	(50) 1 [1.0]	(50) 1 [4.0]	(50)	(50) 1 [2.0]	
Inflammation, Chronic Metaplasia, Osseous Necrosis	2 [1.5] 1 [2.0]		1 [1.0] 1 [3.0]	1 [1.0]	
Alveolar Epithelium, Hyperplasia Alveolus, Infiltration Cellular, Histiocyte Vein, Thrombosis	2 [1.0] 1 [1.0]	5 [1.4] 1 [2.0]	2 [1.0] 1 [2.0] 2 [1.5]	3 [1.7]	

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Nose	(50)	(50)	(50)	(50)	
Inflammation, Suppurative		1 [1.0]			
Inflammation, Chronic	1 [1.0]		2 [1.0]		
Glands, Hyperplasia Glands, Inflammation, Suppurative	1 [1.0]		2 [1.0]		
Nasolacrimal Duct, Infiltration Cellular,	3 [1.3]	1 [1.0]	2 [1.5] 2 [1.5]	1 [1.0]	
Polymorphonuclear	0 [110]	. []	2[0]	. [0]	
Olfactory Epithelium, Atrophy, Focal		2 [2.0]	1 [2.0]	1 [1.0]	
Respiratory Epithelium, Hyperplasia,	1 [1.0]			1 [2.0]	
Focal			4 [4 0]		
Respiratory Epithelium, Necrosis Vomeronasal Organ, Infiltration Cellular,	9 [1.0]	11 [1.0]	1 [1.0] 2 [1.0]	5 [1.0]	
Polymorphonuclear	9 [1.0]	11[1.0]	2 [1.0]	3 [1.0]	
Pleura	(0)	(0)	(1)	(0)	
SPECIAL SENSES SYSTEM					
Eye	(49)	(50)	(49)	(50)	
Degeneration	1 [3.0]	1 [3.0]	(- /		
Cornea, Inflammation, Chronic	1 [2.0]			1 [2.0]	
Retrobulbar, Inflammation, Chronic	1 [2.0]	(50)	(50)	(50)	
Harderian Gland Fibrosis	(49)	(50)	(50)	(50)	
Hyperplasia, Focal	7 [1.9]	4 [1.5]	3 [1.7]	1 [2.0] 5 [1.4]	
riyperplasia, r ocar	7 [1.5]	4 [1.0]	0[1.7]	ر ۱ .۰۱)	
JRINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Hydronephrosis	1 [3.0]	1 [3.0]	(00)	(50)	
Hyperplasia, Lymphoid	1 [2.0]	. [0.0]			
Infarct	2 [2.0]	1 [1.0]	1 [2.0]		
Infiltration Cellular, Lymphoid		1 [3.0]			
Metaplasia, Osseous	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	
Mineralization	6 [1.0]	5 [1.0]	1 [1.0]	3 [1.0]	
Nephropathy	35 [1.1]	23 [1.0]	28 [1.0]	38 [1.1]	
Arteriole, Inflammation, Chronic	4 [0 0]	1 [1.0]			
Artery, Inflammation, Chronic	1 [2.0]			4 [4 0]	
Glomerulus, Amyloid Deposition Renal Tubule, Accumulation, Hyaline	1 [2 0]	2 [2 5]		1 [4.0]	
Renai Tubule, Accumulation, Hyaline	1 [2.0]	2 [2.5]			

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Date Report Regsted: 05/04/2006

Time Report Reqsted: 11:47:08 First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG	
Droplet Renal Tubule, Cyst Urinary Bladder Artery, Inflammation, Chronic	(50)	(50)	(50)	1 [1.0] (50) 1 [3.0]	

*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)